

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GAL EHRLICH
C/O ANTHONY CASTORNIA
2001 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA. 22202

PCT

14 JUL 2005

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year) **26 JAN 2005**

Applicant's or agent's file reference

27434

IMPORTANT NOTIFICATION

International application No.

PCT/IL04/00043

International filing date (day/month/year)

15 January 2004 (15.01.2004)

Priority date (day/month/year)

16 January 2003 (16.01.2003)

Applicant

GALIL MEDICAL LTD.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US

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PATENT COOPERATION TREATY

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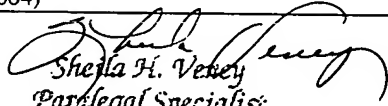
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 27434	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/IL04/00043	International filing date (day/month/year) 15 January 2004 (15.01.2004)	Priority date (day/month/year) 16 January 2003 (16.01.2003)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 5/103, 5/117 and US Cl.: 600/587			
Applicant GALIL MEDICAL LTD.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 17 June 2004 (17.06.2004)	Date of completion of this report 18 January 2004 (18.01.2004)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Max Hindenburg Telephone No. (703) 308-0855 Tech. Center 3700

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-11 _____ as originally filed/furnished
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____

☐ the claims:

pages 12-17 _____ as originally filed/furnished
pages* NONE _____ as amended (together with any statement) under Article 19
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____

☐ the drawings:

pages 1-2 _____ as originally filed/furnished
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International Application No.
PCT/IL04/00043

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 8-10,12,13-18,23-26,30,37-39 and 41 YES

Claims 1-7,11,19-22,27-29,31-36 and 40 NO

Inventive Step (IS)

Claims 8-10,13-18,23-26,30 and 37-39 YES

Claims 1-7,11,12,19-22,27-29,31-36,40 and 41 NO

Industrial Applicability (IA)

Claims 1-41 YES

Claims NONE NO

2. Citations and Explanations (Rule 70.7)

Claims 1, 2, 5-7, 11, 19, 22, 27, 29, 31, 34, 36 and 40 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,865,801 to Houser. Houser discloses an expandable balloon catheter (12) having an expandable balloon (24) which comprises a plurality of strain gauges (Col. 5, lines 45 - 50) mounted external to a wall of the balloon and a data analysis module. The data module comprises a graphics display (Col. 7, lines 23 - 25). The display is capable of displaying an image obtained from an ultrasound system (Col. 6, lines 5 - 26). The strain gauges report strain through a wire connection (Col. 7, lines 20 - 22). Houser discloses a radio-opaque marker (Col. 4, lines 53 - 57).

Claims 1, 5, 6, 11, 19, 34 and 35 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,902,308 to Murphy. Murphy discloses an expandable balloon catheter having an expandable balloon that comprises a plurality of strain gauges mounted in circumferentially on the balloon (Col. 9, lines 12 - 35). The gauges report strain through a wire connection (66).

Claims 1 - 5, 7, 11, 19-22, 27-29, 31-34 and 40 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 6,427,089 to Kowlton. Kowlton discloses an expandable balloon catheter having an expandable balloon that comprises a plurality of strain gauges mounted external, internal and embedded in a wall of the balloon (Col. 15, lines 3 - 10) and a data analysis module (Col. 14, lines 64 - 67). The data module comprises a memory module and a graphics display. The display is capable of displaying an image obtained from a medical imaging modality (Col. 16, line 55 - Col. 17, line 5). The strain gauges report strain through a wire connection.

Claims 12 and 41 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 5,902,308 to Murphy in view of U.S. Patent No. 3,831,588 to Rindner. Murphy discloses the strain gauges reporting strain through a wire connection (66). However, Murphy fails to disclose the strain gauges reporting strain through a wireless connection. Rindner discloses a catheter having a strain gauge that reports strain either through a wire or wireless connection (Col. 2, lines 17 - 20). It would have been obvious to replace the connection as disclosed by Murphy with a wireless connection as taught by Rindner to make the system less cumbersome by removing a wired connection.

Claims 8-10, 13-18, 23-26, 30 and 37-39 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method or system as claimed by applicant.

Claims 1-41 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry related to diagnostic catheters.